29. (new) A method according to claim 24 including allowing the face to move relative to the at least one of the first and second surfaces in a lateral direction.

30. (new) A method according to claim 25 including permitting relative slidable motion between the face and the first surface in a lateral direction.

31. (new) A method according to claim 26 including permitting the face to slidably move relative to the first joint surface in a lateral direction.

REMARKS:

Claims 1-6, 8-10 and 24-31 are pending.

For the convenience of the Examiner, attached at the end of this document is a clean "Claims Appendix" of the current wording of all pending claims.

Also attached hereto is the inventor's Rule 132 Declaration, which forms an integral part of this Amendment.

The claims of the present application are generally directed to treating a degenerated surface on a cancellous bone to grow fibroblast and convert it to fibrocartilage by using a bioresorbable implant, which, amongst others, must permit "slidable motion between the face [of the implant] and the first joint surface" (claim 1). The other independent claims 8 and 24-26 contain similar but not identical recitations, all to the effect that there must be relative slidable motion between the resected joint surface and the corresponding faces of the bioresorbable implant.

New claims 27-31, each of which depends from one of the pending independent claims, further recite that this slidable motion is in a lateral direction, that is, transverse to the longitudinal direction of the adjoining bones.

The present invention, as defined by the independent claims, is useful for biologically reconstituting natural cartilage lost due to arthritis, trauma and the like with fibrocartilage that is a suitable joint (movement) surface for at least nonweight-bearing joints, such as, for example, knuckle joints, the wrist, or the base of the thumb.

Thus, the present invention effects a resurfacing of cancellous bone surfaces with a layer of fibrocartilage that will permit a person to make normal use of the joint.

The basic cell of healing is called the fibroblast and will develop at any site of injury and results from the transformation of a normal blood clot. The fibroblast will go through a series of histological microscopic changes called fibroplasia. The fibroblast on a surface where there is constant motion will change and develop into an entity known as fibrocartilage. This is a white, smooth substance and looks very much like cartilage.

The present invention maintains the mobility of a joint (which has lost its natural cartilage) to promote the generation of a fibrocartilage layer over the resected bone surface. To function substantially like the natural joint, the fibrocartilage layer must have a smooth surface that can slidably move relative to an opposing surface—initially, relative to the opposing surface of the implant and, after the resorption of the implant, relative to the opposing joint surface (which may be natural cartilage or another fibrocartilage grown in accordance with the present invention).

To attain this result, constant motion between the opposing surfaces, generally laterally to the longitudinal direction of the bone, must be maintained while the fibrocartilage forms and the implant is in place.

U.S. patent 5,207,712 ("Cohen") discloses joint implants for the lesser digits and metatarsal phalangeal joints of a foot by first resecting opposing bone ends to expose cancellous bone. An implant (70) (Fig. 10) has a ball (4) (Fig. 1) and solid rods (2) which are integral with and project in opposite directions from the ball. The solid rods are inserted into holes drilled into the respective resected bones. After the solid rods of the implant have been inserted in the drilled holes, ball (4) maintains a spacing between the opposing, resected bone ends. Over time, fibrous tissue forms around the implant and eventually replaces it. Thus, with the implant in place, the opposing resected bone ends (illustrated in Fig. 10) are kept spaced apart by the implant, while the solid rods extend into the previously drilled holes in the bones. Ball (4) determines the size of the gap or spacing between the resected bone ends.

With the implant of Cohen, there is no possibility that the opposing resected surfaces of the bones can slidably move relative to each other. Solid rods (2) are immovably

anchored in the respective holes drilled into the opposing bones. When the bones are moved together (following completion of the operation), ball (4) between the opposing resected bone surfaces is not a slide surface or a pivot point. It is merely a longitudinal spacer. To move one bone relative to the other, at least one of the solid rods necessarily has to be deformed, which is not possible because the Cohen patent states that the rods are solid. Absent such deformation, there is no possibility for the opposing bones to move with respect to each other because implant (70) provides a rigid connection.

The ball located between and engaged by the opposing bones does not constitute a surface with respect to which one or the other bone can slide pivotally. To slide pivotally, it would be necessary to deform at least one of the two solid rods projecting from the ball through an angle which has to correspond in direction and magnitude to the angle of rotation about which the bones are to move with respect to each other. This is an impossibility because the rods are solid and, if attempted, would damage (e.g. break) one or both of the bones in which one or both of the solid rods are anchored.

In the above-referenced Office Action, all independent claims were rejected over Cohen because "the solid sphere and rods allow both for the joint to flex and extend after implantation (see Col. 4, lines 38 and 39) and the ball (4) provides a sliding surface for the joint ends; see the whole document, especially Col. 3, lines 18-20; Col. 4, lines 3-39 and Figures 1-3 and 8-11".

Applicant disagrees. The solid sphere and rods do not allow the adjacent bones to flex or extend after implantation. Column 4, lines 38 and 39 of Cohen do not support this conclusion. Lines 37-39 state:

> "After placement, the stability and position of the toe is checked. Flexion and extension of the joint should not result in dislocation of the implant."

This does not mean that the resected bone surfaces can flex with respect to each other after the solid sphere and rods have been implanted. This statement means that the Cohen implant is intended to prevent action, i.e. flexion and extension, because the goal is a

fusion of the joint and not the creation of a flexible (articulating) joint. The inventor is a person skilled in the art, and his attached Rule 132 Declaration confirms this conclusion.

Moreover, this is the only possible result when using the implant of Cohen. The Cohen patent nowhere states or in any form suggests that the use of the implant leads to an articulating joint. Quite to the contrary, Cohen states amongst others that the "metatarsal implant of a biodegradable substance ... would eventually be replaced by mature fibrous tissue" (column 2, lines 26-28). A similar statement appears in column 2, lines 45-47 of Cohen. These statements mean, and are understood by those skilled in the art to mean, that the joint between the opposing bones is eventually replaced by fibrous tissue, but this fibrous tissue does not have cooperating, articulating surfaces, as is confirmed by the attached Rule 132 Declaration.

Cohen's statement that "flexion and extension of the joint should not result in dislocation of the implant" (column 2, lines 38-39) means that when the patient flexes or extends the tow, the resulting forces applied to the implant should not result in its dislocation. In other words, the implant must be capable of withstanding such forces, thereby preventing motion and enabling a fusion of the bones by growing fibrous tissue between them. This is confirmed by the attached Rule 132 Declaration.

The above-referenced Office Action states that "the Examiner posits that one viewing this embodiment would be led to the conclusion that the ball (4) obviously functions as a stop and sliding surface for the resected bone ends because the joint flexes and extends around the ball surface; see column 4, lines 38-39". For the reasons stated in the preceding paragraphs, applicant disagrees that any part of Cohen suggests that the ball (4) does or can act as a sliding surface for the resected bone ends. In Cohen, the resected bone ends cannot move with respect to each other, particularly in a lateral direction perpendicular to the longitudinal extent of the bones. This is confirmed by the attached Rule 132 Declaration.

In the above-referenced Office Action, "the Examiner posits that 'the joint' must refer to the joint containing an implant because no other joint is the topic of discussion in the context of the disclosure text". In the context of the disclosure of Cohen, and in particular the text in column 4, lines 38-39, the "joint" referred to there is not the implanted ball (4) and

solid rods (2), but refers instead to a fibrous union between the resected bone ends which joins the resected bone ends after the implant (ball (4) and solid rods (2)) have resorbed, as is confirmed by the attached Rule 132 Declaration.

In the above-referenced Office Action, "the Examiner asserts that this process [the formation of fibroblast and fibrocartilage] would also occur in the Cohen healing process because joint motion is also provided thereby as pointed out above". Applicant disagrees. The Cohen implant does not permit any relative slidable motion between the resected bone surfaces. Permitting such motion is not the intended goal of Cohen, and Cohen contains no suggestion how to form a movable joint between opposing at least partially resected bone surfaces formed by fibrocartilage. This too is confirmed by the attached Rule 132 Declaration.

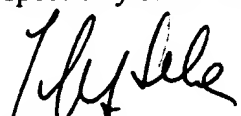
Thus, Cohen does not disclose or in any form suggest to one of ordinary skill in the art to place a bioresorbable implant between and in contact with the first and second joint surfaces (as the term is used in claim 1, for example), so that the face [formed by the removed portion of the first joint surface] is opposite the first joint surface and the implant initially keeps the exposed cancellous bone surfaces apart from the second joint first surface while permitting slidable motion between the face and the first joint surface. Cohen discloses to one of ordinary skill in the art only to implant solid rods into opposing bones and providing a spacer, for example ball (4), to keep the resected bone surfaces apart. Once this implant is in place, the opposing bone surfaces are prevented from moving relative to each other, particularly in the lateral direction, as is confirmed by the attached Rule 132 Declaration.

Thus, Cohen does not anticipate, or render obvious, any of the pending independent claims 1, 8 and 24-31. The depending claims are therefore also allowable.

In view of the foregoing, applicant submits that this application is now in condition for allowance. The issuance of a formal notification to that effect at an early date is requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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